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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,626	09/29/2003	Michel Cormier	33392-712.201	4707

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

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11/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,626	CORMIER ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 21-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *9* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/30/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' IDS filed 05/30/2007; and amendment filed 09/11/2007.

Claims 1-39 are pending.

Response to Election/Restrictions

This application contains claims 1-8 and 21-39 are drawn to an invention nonelected with traverse in the reply filed on 02/28/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 9-20 are included in the prosecution.

The following rejection has been overcome by virtue of applicants' amendment and remarks:

The rejection of claim 11 under 35 U.S.C. 112, second paragraph as being indefinite.

The following rejections have been discussed in details in the previous office action and are maintained for reasons of record:

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 11/259,010. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the conflicting claims of the copending application are directed to device for transdermal delivery of active agent comprising microprojections coated with the active agent and vasoconstrictor, recited by claim 17 of the copending application. The present claims and the copending claims are obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 11/201,617. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the conflicting claims of the copending application are directed to device for transdermal delivery of active agent comprising microprojections coated with the active agent and vasoconstrictor, recited by claim 16 of the copending application. The present claims and the copending claims are obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-81 of copending Application No. 11/084,636. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the conflicting claims of the copending application are directed to device for transdermal delivery of active agent comprising microprojections coated with the active agent and vasoconstrictor, recited by claims 21, 22, 68 and 69of the copending application. The present claims and the copending claims are obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

5. Applicant's arguments filed 09/11/2007 have been fully considered but they are not persuasive. Applicants request that the double patenting rejections be stayed in abeyance until the present application is indicated to be otherwise allowable. At such time, Applicants will submit a Terminal Disclaimer, if appropriate.

However, the "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications. If the "provisional" double patenting rejection in one application is the only remaining rejection in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other applicant into a double patenting rejection at the time the one application issues as a patent.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 9-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/074173 ('173) in view of US 6,432,986 ('986).

WO '173 teaches apparatus for transdermal application of bioactive agent to the skin. The apparatus comprises plurality of microprojections coated with dry coating comprising active agents (abstract; paragraphs: 0007, 00039). The active agents is present in the coating in an amount less than 1 mg and include vaccine, LHRH, PTH, vasopressin, ACTH (1-24), interferon, EPO, FSH, GM-CSF, G-CSF, IL10 (paragraph 00014). The microprojections have length of less than 500 μm, thickness of 5-50 microns (paragraph 0037). The thickness of the coating on the microprojections is less than 25 μm, and preferably less than 10 μm (paragraph 00013). The coating may further comprise an adjuvant (paragraph 00057).

The difference between WO '173 and the present invention is that the WO '173 does not teach vasoconstrictors delivered from the coating with the active agent as claimed by claims 9 and 20, or its amount as claimed by claim 13.

US 986 teaches transdermal drug delivery wherein vasoconstrictor such as epinephrine in amount of 5 microgram per milliliter is added to drug in order to reduces the rate of drug absorption and prolongs the duration of its effect (col.6, lines 37-47).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide apparatus for transdermal application of bioactive agent to the skin comprises plurality of microprojections coated with dry coating comprising active agents and adjuvant as disclosed by WO '173, and replace the adjuvant with vasoconstrictor agent as disclosed by US '986, motivated by the teaching of US '986 that vasoconstrictor when added to transdermally delivered drug, it reduces the rate of drug absorption and prolongs the duration of its effect, with reasonable expectation of having apparatus for transdermal application of bioactive agent to the skin comprises plurality of microprojections coated with dry coating comprising active agents and vasoconstrictor that reduces the rate of drug absorption and prolongs the duration of its effect successfully.

Response to Arguments

9. Applicant's arguments filed 09/11/1007 have been fully considered but they are not persuasive. Applicants argue that the combination of WO '173 and the '986 patent fails to suggest each feature of the presently claimed invention. Neither WO '173, nor

the '986 patent disclose coating is disposed on at least one of the plurality of stratum corneum-piercing microprotrusions to release the vasoconstrictor into the skin when the coating is dissolved, resulting in the inhibition of bleeding and a decrease in blood flow at the site of application of said device. Moreover, neither WO ' 173, nor the '986 patent suggest the advantages obtained by the present invention. Illustration of such advantages is provided in Example 1 and Figures 3-5 discussed therein.

In response to this applicant's argument, it is argued that the prior art WO '173 teaches vasopressin (vasoconstrictor) as one of the active agents that can be coated on the microprojections, however, not in combination with other active agents. US '986 recognized the combination of vasoconstrictors with other drugs delivered through the skin. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one having ordinary skill in the art would have been motivated to replace the adjuvant with vasoconstrictor or further add vasoconstrictor to the coating of the microprotrusions of the device disclosed by WO '173 because WO '173 teaches the vasopressin is suitable for application as a coating for microprotrusion and US '986 teaches that vasoconstrictor when added to transdermally delivered drug, it reduces the rate of drug absorption and prolongs the

duration of its effect, with reasonable expectation of having apparatus for transdermal application of bioactive agent to the skin comprises plurality of microprojections coated with dry coating comprising active agents and vasoconstrictor that reduces the rate of drug absorption and prolongs the duration of its effect successfully. Vasoconstrictors disclosed in the coating of WO '173, and are expected to be released from the coating when coating contacts and dissolves in the body fluids. Vasoconstrictors will inhibit bleeding because drugs and their functions are inseparable. The invention as a whole is taught y the combined teachings of the references because the present invention is directed to product and all the elements of the product are disclosed by the combined teachings of the references. In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require

absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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PRIMARY EXAMINER